

147
-45-

CLAIMS

What is claimed is:

- 5 1. A composition comprising OspC polypeptides from Lyme Disease causing *Borrelia* wherein either:
- 10 a) said composition comprises one or more OspC polypeptides or immunogenic fragments thereof from at least two *Borrelia burgdorferi* OspC families selected from the group consisting of: A, B, I and K, excepting the combination consisting of two OspC proteins wherein one OspC protein is from family A and the second OspC protein is from family I, or;
- 15 b) said composition comprises at least one OspC polypeptide or immunogenic fragment thereof from each of *Borrelia afzelii* OspC families A and B.
2. The composition of Claim 1 comprising one or more OspC polypeptides or fragments thereof from each of *Borrelia burgdorferi* families of the group of subpart a).
3. The composition of Claim 1, wherein said OspC polypeptide or fragment thereof comprises the OspC protein variable region.
- 20 4. The composition of Claim 3, wherein said OspC polypeptide or fragment thereof is encoded by a nucleic acid comprising nucleotide 26 to about nucleotide 621 of an *ospC* gene.

00596745-064000

149
-47-

gene OC12 and OC13, wherein strain 297 is characterized by *ospC* of GenBank accession number U08284.

12. The composition of Claim 1, wherein *Borrelia afzelii* OspC family A comprises strains Pbo, Pwud, PKO, Pgau, DK2, DK3, DK21, DK8, Bfox and JSB.
- 5 13. The composition of Claim 1, wherein *Borrelia afzelii* OspC family B comprises strains DK5, ACA1, DK9, XB18h, Ple and 134M.
14. A method of immunizing an animal against Lyme disease, comprising administering a composition comprising at least two OspC polypeptides from Lyme Disease causing *Borrelia* wherein either:
- 10 a) said composition comprises one or more OspC polypeptides or fragments thereof from at least two *Borrelia burgdorferi* OspC families selected from the group consisting of: A, B, I and K, excepting the combination consisting of two OspC proteins wherein one OspC protein is from OspC family A and the second OspC protein is from OspC
- 15 b) said composition comprises at least one OspC polypeptide or fragment thereof from each of *Borrelia afzelii* OspC families A and B.
15. The method of Claim 14, wherein the composition comprises one or more OspC polypeptides or fragments thereof from each of *Borrelia burgdorferi* families of
- 20 the group of subpart a).
16. The method of Claim 14, wherein said OspC polypeptide or fragment thereof comprises the OspC protein variable region.

006790 94296560

150
-48-

17. The method of Claim 14, wherein said OspC polypeptide or fragment thereof is encoded by a nucleic acid comprising nucleotide 26 to about nucleotide 621 of an *ospC* gene.
18. The method of Claim 14, wherein said OspC polypeptide or fragment thereof is encoded by a nucleic acid comprising nucleotide 53 to about nucleotide 570 of an *ospC* gene.
19. The method of Claim 14, wherein at least two of said OspC polypeptides or immunogenic fragments thereof are fused together in a single protein, encoded by a single nucleic acid, wherein polypeptides in said fusion protein are not found in the same configuration in a naturally occurring OspC protein.
20. The method of Claim 14, wherein the *ospC* gene encoded the OspC polypeptides within a given OspC family are at least 98% identical at the nucleic acid level.
21. The method of Claim 14, wherein *Borrelia burgdorferi* OspC family A comprises strains B31, CA4, HII, IPI, IP2, IP3, L5, PIF, Pka, Txgw and strains containing *ospC* allele OC1.
22. The method of Claim 14, wherein *Borrelia burgdorferi* OspC family B comprises strains 35B808, 61 BV3, BUR, DK7, PB3, Z57 and strains containing *ospC* genes OC2 and OC3.

0959746-064900
0959746-064900

151
~~49~~

23. The method of Claim 14, wherein *Borrelia burgdorferi* OspC family I comprises strains 297, HB19 and strains containing *ospC* gene OC10, wherein strain 297 is characterized by *ospC* of GenBank accession number L42893.
24. The method of Claim 14, wherein *Borrelia burgdorferi* OspC family K comprises strains 272, 297, 28354, KIPP, MUL and strains containing *ospC* gene OC12 and OC13, wherein strain 297 is characterized by *ospC* of GenBank accession number U08284.
25. The method of Claim 14, wherein *Borrelia afzelii* OspC family A comprises strains Pbo, Pwud, PKO, Pgau, DK2, DK3, DK21, DK8, Bfox and JSB.
26. The method of Claim 14, wherein *Borrelia afzelii* OspC family B comprises strains DK5, ACA1, DK9, XB18h, Ple and 134M.
27. A method of detecting an immune response to Lyme Disease causing *Borrelia* in a host sample, comprising;
- a) contacting the host sample with a composition comprising OspC polypeptides from Lyme disease causing strains of *Borrelia*, such that anti-OspC antibodies, if present in said sample bind to said OspC polypeptides; wherein
 - i) said composition comprises one or more OspC polypeptides or fragments thereof from at least two *Borrelia burgdorferi* OspC families selected from the group consisting of: A, B, I and K, excepting the combination consisting of two OspC proteins wherein one OspC protein is from family A and the second OspC protein is from family I, or;

152
~~50~~

- ii) said composition comprises at least one OspC polypeptide or fragment thereof from each of *Borrelia afzelii* OspC families A and B; and
- b) detecting antibodies that have bound said OspC peptides; thereby detecting an immune response to Lyme disease causing *Borrelia*.
- 5
28. The method of Claim 27, wherein said OspC polypeptide or fragment thereof comprises the OspC protein variable region.
29. The composition of Claim 27, wherein said OspC polypeptide or fragment thereof is encoded by a nucleic acid comprising nucleotide 26 to about nucleotide 621 of an *ospC* gene.
- 10
30. The composition of Claim 27, wherein said OspC polypeptide or fragment thereof is encoded by a nucleic acid comprising nucleotide 53 to about nucleotide 570 of an *ospC* gene.
31. The composition of Claim 27, wherein at least two of said OspC polypeptides or immunogenic fragments thereof are fused together in a single protein, encoded by a single nucleic acid, wherein polypeptides in said fusion protein are not found in the same configuration in a naturally occurring OspC protein.
- 15
32. The method of Claim 27, wherein the *ospC* genes encoding the OspC polypeptides within a given OspC family are at least 98% identical at the nucleic acid level.
- 20

005790-061000

153
-51-

33. The method of Claim 32, wherein *Borrelia burgdorferi* OspC family A comprises strains B31, CA4, HII, IPI, IP2, IP3, L5, PIF, Pka, Txgw and strains containing *ospC* allele OC1.
34. The method of Claim 32, wherein *Borrelia burgdorferi* OspC family B comprises strains 35B808, 61 BV3, BUR, DK7, PB3, Z57 and strains containing *ospC* genes OC2 and OC3.
35. The method of Claim 32, wherein *Borrelia burgdorferi* OspC family I comprises strains 297, HB19 and strains containing *ospC* gene OC10, wherein strain 297 is characterized by *ospC* of GenBank accession number L42893.
36. The method of Claim 32, wherein *Borrelia burgdorferi* OspC family K comprises strains 272, 297, 28354, KIPP, MUL and strains containing *ospC* gene OC12 and OC13, wherein strain 297 is characterized by *ospC* of GenBank accession number U08284.
37. The method of Claim 32, wherein *Borrelia afzelii* OspC family A comprises strains Pbo, Pwud, PKO, Pgau, DK2, DK3, DK21, DK8, Bfox and JSB.
38. The method of Claim 32, wherein *Borrelia afzelii* OspC family B comprises strains DK5, ACA1, DK9, XB18h, Ple and 134M.
39. A chimeric protein comprising OspC polypeptides from two or more Lyme Disease causing OspC families of Lyme Disease causing *Borrelia* wherein said chimeric protein comprises:

sub
B6

154
-52-

- 5
- a) a first OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 26 to about nucleotide 621 of an *ospC* gene from a first OspC family and
 - b) a second OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 28 to about nucleotide 570 of an *ospC* gene from a second OspC family.

40. The chimeric protein of Claim 39, wherein said OspC families are selected from the group consisting of: *Borrelia burgdorferi* OspC families A, B, I and K, and *Borrelia afzelii* OspC families A and B.

10 41. A chimeric protein comprising OspC polypeptides from two or more Lyme Disease causing OspC families of Lyme Disease causing *Borrelia* wherein said chimeric protein comprises:

- 15
- a) a first OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 53 to about nucleotide 570 of an *ospC* gene from a first OspC family and
 - b) a second OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 28 to about nucleotide 570 of an *ospC* gene from a second OspC family.

42. The chimeric protein of Claim 41, wherein said protein is unlipidated.

20 43. A chimeric OspC protein selected from the group consisting of: SEQ Id Nos: 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84 and 86.

155
-53-

44. An isolated nucleic acid encoding a chimeric protein wherein said protein comprises OspC polypeptides from two or more Lyme Disease causing OspC families of Lyme Disease causing *Borrelia* wherein said chimeric protein comprises:
- 5 a) a first OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 26 to about nucleotide 621 of an *ospC* gene from a first OspC family and
- b) a second OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 28 to about nucleotide 570 of an *ospC* gene from a second OspC family.
- 10
45. The nucleic acid of Claim 44, wherein said OspC families are selected from the group consisting of: *Borrelia burgdorferi* OspC families A, B, I and K, and *Borrelia afzelii* OspC families A and B.
46. The nucleic acid of Claim 44, wherein said protein is unlipidated.
- 15 47. A isolated nucleic acid comprising OspC polypeptides from two or more Lyme Disease causing OspC families of Lyme Disease causing *Borrelia* wherein said isolated nucleic acid comprises:
- a) a first OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 53 to about nucleotide 570 of an *ospC* gene from a first OspC family and
- 20 b) a second OspC polypeptide encoded by a nucleic acid comprising a sequence from about nucleotide 28 to about nucleotide 570 of an *ospC* gene from a second OspC family.

00596746-06400

156
~~54~~

48. An isolated nucleic acid selected from the group consisting of : SEQ ID Nos:
23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 51, 53, 55, 56, 59, 61, 63, 65, 67, 69, 71,
73, 75, 77, 79, 81, 83 and 85.

00506745-061900